Remarks

Rejection under 35 U.S.C. § 112, first paragraph

Claims 30-33 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims. The Action alleges that the specification does not enable all soluble proteins, fragments or mutants generated from any position located on the ss3939 protein. The Action also alleges there is no guidance as to how the functional fragments and mutants can be generated, the positions in the protein that are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. Further, the Action alleges that without knowing the function of a soluble polypeptide ss3939 variant it would require undue experimentation to make variants that are 90% or 95% identical to amino acids 22-227 of SEQ ID NO: 2 that bind to human umbilical vein endothelial cells.

Applicant respectfully traverses these grounds for rejection. The Action has provided no evidence that the alleged experimentation would be beyond that which is considered routine to one of skill in the art. MPEP 2164.06 provides that "a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed".

The specification provides structural information useful for identifying regions to be considered for producing soluble polypeptides, such as the extracellular and intracellular domains, see pages 10-11. Also provided are methods that are known and used by those skilled in the art to make the sequences of the claimed invention. For example, percent identity can be determined visually, mathematically or by computer programs and algorithms, see pages 15-16. Applicant has also provided an analysis prepared using such methods and information known to those of skill in the art at the time of filing. Exhibit 2 provided in response to the Action dated 1/16/2004, clearly discerned the residues of ss3939 polypeptide that were involved in the binding activity. Such information is useful to one of skill in the art to identify positions that are tolerant to change and the nature and extent of changes that could

be made in those positions. As for the function of the soluble polypeptides of the invention, the specification provides binding assays that one of skill in the art could easily use to identify and characterize the binding of such polypeptides, see for example on pages 34-36. Example 5 also provides a working example. The disclosed soluble polypeptide ss3939/Fc could even be used as a positive control for determining human umbilical vein endothelial cell binding of other soluble polypeptides.

Since a considerable amount of routine experimentation is permissible and the Action provides no evidence that the alleged experimentation would be beyond that which is considered routine to one of skill in the art, Applicant respectfully submits that for at least the reasons stated above, the rejection of claims 30-33 under 35 U.S.C. §112, first paragraph has been traversed and withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 14, 24 and 30 and the dependent claims thereto are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. The alleged omitted essential steps are: bringing the polypeptide to the contact of a binding partner; inhibition of binding step; the ultimate biological effects that result from inhibiting ss3939 polypeptide binding with a binding partner.

Applicant respectfully traverses these grounds for rejection. The cited reference to MPEP § 2172.01 does not specify a rejection under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps. MPEP § 2172.01 does provide for rejections under 35 U.S.C. § 112, first paragraph for omission of matter disclosed to be essential to the invention as described in the specification. Essential matter is described as including missing elements or steps. MPEP § 2172.01 also provides for rejection under 35 U.S.C. § 112, second paragraph as failing to interrelate essential elements of the invention as defined by Applicant in the specification.

Regardless of which rejection was intended, the Action does not point to support in the specification where the alleged "omitted steps" are either disclosed to be essential to the invention or have been defined by Applicant as essential elements of the invention, as is required under either 35 U.S.C. § 112, first paragraph or second paragraph.

Therefore, for at least these reasons, Applicant respectfully requests that the rejection under 35 U.S.C. § 112, second paragraph, be withdrawn.

Rejection under 35 U.S.C. § 102(e)

Claims 30, 31, 32 and 33 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Komatsoulis et al. (US Patent 6,476,195).

Applicant respectfully traverses these grounds for rejection. For anticipation under U.S.C § 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present. The Action makes the 102(e) rejection based on the protein designated by Komatsoulis et al. as "HOEEU24" having amino acid residues 1-374 of SEQ ID NO: 166 encoded by Gene 40. The Action expressly states "[t]he polypeptide of this gene has a transmembrane domain and shares structural features to type Ia membrane proteins (col 74 and 75)...", emphasis added.

Claim 30 of Applicant's invention recites in part, "the method comprising providing an isolated **soluble** polypeptide..." emphasis added. Soluble polypeptides are defined in Applicant's specification on pages 14 and 15 as:

> "capable of being secreted from the cells in which they are expressed. In general, soluble polypeptides may be identified (and distinguished from non-soluble membrane-bound counterparts) by separating intact cells which express the desired polypeptide from the culture medium, e.g., by centrifugation, and assaying the medium (supernatant) for the presence of the desired polypeptide. The presence of the polypeptide in the medium indicates that the polypeptide was secreted from the cells and thus is a soluble form of the protein. In one embodiment, the soluble polypeptides and fragments thereof comprise all or part of the extracellular domain, but lack the transmembrane region that would cause retention of the polypeptide on the cell membrane. " Emphasis added.

Applicant submits that Komatsoulis et al. does not anticipate claims 30-33 because the protein cited in the Action is a type Ia membrane protein whereas Applicant's invention specifically requires an isolated soluble polypeptide.

Therefore, for at least these reasons, Applicant respectfully requests that the rejection under 35 U.S.C. § 102(e), be withdrawn.

CONCLUSION

Applicant submits that the presented claims are in condition for allowance. A favorable action is earnestly requested. Applicant's attorney invites the Examiner to call her at the number below if any issue remains outstanding.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence if being deposited with the United States Postal Service as first class mail in an envelope addressed to the Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date appearing below.

January 25, 2005
Date

Kathleen F. Pfindle

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